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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	8

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,214	LIPMAN, ROGER D.A.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The receipt is acknowledged of applicant's amendment B, filed 07/25/2003.

Non-elected claims 6 and 17-20 have been canceled without prejudice.

Claims 1-5 and 7-16 are included in the prosecution.

Specification

1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-5 and 7-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites that the discontinuous phase comprises cyclodextrin in an amount of 0.1 to 60 wt % and also comprises a hydrocolloid other than cyclodextrin, while in the specification, page 13, first paragraph,

applicant disclosed that the amount of 0.1 to 65 wt % includes the combined amount of cyclodextrin and another hydrocolloid. Clarification is requested.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-5 and 7-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,231,369 ('369) in view of US 5,817,332 ('332).

US '369 teaches an adhesive sealing material for use in connection to ostomy devices composed of continuous rubber phase and hydrocolloid dispersed in the continuous phase, i.e. forming discontinuous phase (abstract; col.4, lines 30-31, 55-60). The rubber phase is made of styrene copolymer and polyisobutylene wherein the styrene copolymer forms 40 wt % or below of the of the rubber (col.5, lines 8-10, 36-37, 46). Example O, Table III, shows that he styrene copolymer "Cariflex" forms 10.9% of the composition, and polyisobutylene forms 18.1 % of the composition. The hydrocolloid is a mixture of more than one hydrocolloid in an amount ranges from 48-56 % (col.8, lines 52-54). The composition further comprises oils, medicaments, or bactericides (col.6, lines 33, 45-47). The composition is supplied by release liner, i.e. substrate (col.9, lines 1-2).

The reference does not list cyclodextrin among the hydrocolloids, or the material of the backing.

The non-adhesive water proof backing are well known in the art, and are widely used for wound dressings and transdermal drug delivery devices.

US '332 teaches a transdermal device for the delivery of therapeutic agent comprises the drug complexed with cyclodextrin to enable steady state of drug release because cyclodextrin increase the water solubility of many drugs by complexing them into the hydrophobic cavity of the cyclodextrin (abstract; col.2, lines 52-56, 63-64; col.4, lines 37-39). The device comprises the cyclodextrin drug complex forming plurality of cores dispersed in a polymer matrix and a backing layer (col.3, lines 50-53, 60; col.5, lines 21-30). The drug includes antibacterial agents (col.5, line 5).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a composition comprising continuous rubbery phase and discontinuous hydrocolloid phase as disclosed by US '369, and replace the hydrocolloid by cyclodextrin complexed with drugs as disclosed by US '332, motivated by the teaching of US '332 that drugs complexed with cyclodextrin enable steady state of drug release because cyclodextrin increase the water solubility of many drugs by complexing them into the hydrophobic cavity of the cyclodextrin, with reasonable expectation of having a composition comprising rubbery continuous phase and cyclodextrin discontinuous phase that release drug from the devices containing the composition at steady controlled rate with success.

6. Claims 1-5 and 7-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,367,732 ('732) in view of US '332.

US '732 teaches a skin barrier comprises an adhesive layer comprising discontinuous hydrocolloid phase dispersed in a continuous phase comprising styrene copolymers and polyisobutylene (abstract; col.5, lines 24-26, 49; col.6, lines 35-36; col.8, lines 31-42, 62-64). The adhesive composition further comprises bacteriostatic or fungicidal agents (col.6, line 59). The hydrocolloid phase comprises at least one hydrocolloid, and forms 10-55% of the composition of the adhesive layer (col.8, lines 53-55; col.9, lines 22-23). The styrene copolymer forms 10-40% of the continuous phase (col.9, line 16). The skin barrier further comprises a non-adhesive, water impervious film secured to the adhesive layer (col.3, lines 54-56).

The reference does not list cyclodextrin among the hydrocolloids.

US '332 teaches a transdermal device for the delivery of therapeutic agent comprises the drug complexed with cyclodextrin to enable steady state of drug release because cyclodextrin increase the water solubility of many drugs by complexing them into the hydrophobic cavity of the cyclodextrin (abstract; col.2, lines 52-56, 63-64; col.4, lines 37-39). The device comprises the cyclodextrin drug complex forming plurality of cores dispersed in a polymer matrix and a backing layer (col.3, lines 50-53, 60; col.5, lines 21-30). The drug includes antibacterial agents (col.5, line 5).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a composition comprising continuous rubbery phase and discontinuous hydrocolloid phase as disclosed by US '732, and replace the

hydrocolloid by cyclodextrin complexed with drugs as disclosed by US '332, motivated by the teaching of US '332 that drugs complexed with cyclodextrin enable steady state of drug release because cyclodextrin increase the water solubility of many drugs by complexing them into the hydrophobic cavity of the cyclodextrin, with reasonable expectation of having a composition comprising rubbery continuous phase and cyclodextrin discontinuous phase that release drug from the devices containing the composition at steady controlled rate with success.

7. Claims 1-5 and 7-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/14282 ('282) in view of US '332.

WO '282 teaches a pressure sensitive adhesive material comprising continuous phase of rubber comprising styrene copolymer and polyisobutylene; and a discontinuous phase comprising hydrocolloid (abstract). The discontinuous phase forms 15-70 wt % of the composition (page 11, first paragraph). The styrene copolymer forms 10-30 wt % of the composition, and the polyisobutylene forms 20-60 wt % of the composition (page 15, claims 1-4). Example 2, page 13, shows that the composition comprising more than one hydrocolloid. The composition comprises bactericides (page 11, third paragraph). The adhesive composition is coated on non-adhesive waterproof film and used in adhesive barrier or dressing for medical use (page 16, claim 13).

The reference does not list cyclodextrin among the hydrocolloids.

US '332 teaches a transdermal device for the delivery of therapeutic agent comprises the drug complexed with cyclodextrin to enable steady state of drug release

because cyclodextrin increase the water solubility of many drugs by complexing them into the hydrophobic cavity of the cyclodextrin (abstract; col.2, lines 52-56, 63-64; col.4, lines 37-39). The device comprises the cyclodextrin drug complex forming plurality of cores dispersed in a polymer matrix and a backing layer (col.3, lines 50-53, 60; col.5, lines 21-30). The drug includes antibacterial agents (col.5, line 5).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a composition comprising continuous rubbery phase and discontinuous hydrocolloid phase as disclosed by WO '282, and replace the hydrocolloid by cyclodextrin complexed with drugs as disclosed by US '332, motivated by the teaching of US '332 that drugs complexed with cyclodextrin enable steady state of drug release because cyclodextrin increase the water solubility of many drugs by complexing them into the hydrophobic cavity of the cyclodextrin, with reasonable expectation of having a composition comprising rubbery continuous phase and cyclodextrin discontinuous phase that release drug from the devices containing the composition at steady controlled rate with success.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone

number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615

ISIS GHALI
PATENT EXAMINER

Isis Ghali